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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

MICHAEL HOUGHTON *et al.*

Serial No.: 08/441,355

Group Art Unit: 1815

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Examiner: M. Zeman

For: NANBV DIAGNOSTICS AND VACCINES

**INFORMATION DISCLOSURE STATEMENT**

**UNDER 37 CFR §1.56, §1.97 AND §1.98**

Assistant Commissioner for Patents & Trademarks  
Washington, D.C. 20231

Dear Sir:

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day of April, 1997  
By Oliver O. Mlinar*

The information listed below, may be material to the examination of the above-identified application. All of the information below was previously considered by a U.S. Examiner during the prosecution of applications from which this application takes priority. Some information that was considered in a previous related application 08/103,961 ("the '961 application") has not been listed in this IDS in an effort to facilitate the Examiner's review of the application and relevant materials. The Examiner may, nonetheless, wish to review the December 1993 information disclosure statement filed in the '961 application.

Section I is a comprehensive list of all the information to be made of record in an Information Disclosure Statement in this application. Section I.A. contains information previously submitted to the PTO but that which was cited for the first time during the prosecution of U.S. Serial No. 08/307,273, the parent of the present application. Information listed in Section I.B. was cited during the prosecution of earlier related applications. Information that is listed below and which has been considered or provided in earlier applications (cited in Sections I.A. and I.B.) is listed on the attached PTO-1449, but copies have not been provided

pursuant to 37 CFR §1.98(d). Section II lists the information from Sections I.A. and I.B. relating to the inventorship of the application. For the ease of the Examiner, cross-references to the earlier applications and reference number in the IDS or Examiner's Action have been provided.

There have been rejections during prosecution of pending applications and a number of attacks on the validity of corresponding foreign patents and allowed applications. Sections III to VI organize the information in Section I based on the forum and foreign application patents under attack. The Examiner can use Sections III to VI as a guide to the material cited in Section I and II. Rejections and other attacks have been made in the form of, inter alia, written argument, document citations and substantive testimony, including declarations and affidavits. While these attacks are believed to be without merit, it is believed by applicants that this information should be submitted to the Examiner out of an abundance of caution. The best explanation of these attacks is believed to be found in the various written arguments, pleadings, opposition statements and witness statements that accompany the attacks. Relevant selections from applicants' responsive pleadings, opposition replies, and witness statements that set out applicants' views of the various statements are likewise submitted herewith. The Examiner should also consult contemporaneous review articles regarding the state of the art at the time the invention was made, many of which have been previously submitted.

The Examiner is respectfully requested to make all of this information of official record in the application.

For the Examiner's convenience, the information has been organized as follows:

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**I. COMPLETE LIST OF ALL INFORMATION SUBMITTED IN THIS APPLICATION**

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- I.A.101. Second Opposition to Chiron Japanese Patent Application No. 01-500565, filed by Akira Yamamoto (and translation) with supporting documents including:  
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- I.A.103. Third Opposition to Chiron Japanese Patent Application No. 01-500565, filed by Asako Sudo (and translation) with supporting documents including:  
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- I.A.114. Reply to Eighth Opposition to Chiron Japanese Patent Application  
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- I.A.115. Ninth Opposition to Chiron Japanese Patent Application No. 01-  
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- I.A.116. Reply to Ninth Opposition to Chiron Japanese Patent Application  
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- I.A.117. Tenth Opposition to Chiron Japanese Patent Application No. 01-  
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- Diagram showing the relationship between a main epitope in the C7 region and an epitope consisting of 8 amino acids reported by Dr. Geysen
- Experimental Report by Assistant Professor K. Kiyosawa from Shinsu University Medical Department
- Table A showing the reactivity of the C-7 Antigen Region
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- I.A.121. Twelfth Opposition to Chiron Japanese Patent Application No. 01-500565, filed by Shigeo Kimura (and translation) with supporting documents including:
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- I.A.126. Reply to Fourteenth Opposition to Chiron Japanese Patent Application No. 01-500565
- I.A.127. Translation of Decision on Opposition Against Patent Application No. 01-500565, issued 12/22/95.
- I.A.128. Statement of Grounds for Opposition to Australian Patent No. 640,920, filed by Hoffman La Roche, including:
- Notice of Opposition
- Statutory Declaration of Eric James Gowans (9/8/94) in the Opposition to Australian Patent No. 640,920

**[Volume 10]**

- I.A.129. Australian Litigation Bundle, for Chiron Australian Patent No. 624,105, which includes:
- Amended Particulars of Invalidity (1995) in the Litigation of Australian Patent No. 624,105
- Application- with Statement of Claims and Particulars of Invalidity (03/03/94) in the Litigation of Australian Patent No. 624,105
- Particulars of Infringement (06/10/94) in the Litigation of Australian Patent No. 624,105
- Affidavit of Patrick Robert Carnegie (12/13/94)
- Affidavit of Peter Malcolm Colman (12/15/94)
- Affidavit of Eric James Gowans (12/15/94)
- Affidavit of Lacy R. Overby (8/19/94)
- Affidavit of Daniel W. Bradley (4/5/95)
- Affidavit of George Kuo (10/23/95)
- Affidavit of Robert Tjian (10/31/95)
- Affidavit of Amy Joan Weiner (11/1/95)
- Affidavit of Michael Steven Urdea (11/6/95)
- Affidavit of Michael Houghton (11/29/95)
- Affidavit of Gregory R.Reyes (12/05/94)
- Affidavit of Stephen Alister Locarnini (12/08/94)
- Affidavit of David James Kemp (12/07/94)
- Affidavit of Ian David Gust (12/05/94)
- Affidavit of Stephen M. Feinstone (08/11/94)

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- Affidavit of Lynn Dalgarno (12/08/94)
- Affidavit of Patrick Robert Carnegie (12/08/94)
- Affidavit of Baruch S. Blumberg (12/01/94)
- Affidavit of Terukatsu Arima (12/07/94)
- Affidavit of Peter Malcolm Colman (12/15/94)
- Affidavit of Michael Joseph McGarvey (10/30/95)
- Affidavit of John Shine (12/04/95)

Affidavit of Sir Gustav Nossal (12/12/95)  
Affidavit of John Mills (12/06/95)  
Affidavit of Robert William Beal (11/20/95)  
Affidavit of Gerald Wayne Both (11/24/95)  
Affidavit of Stephen R. Lee (10/24/95)  
Affidavit of Christopher John Burrell (11/20/95)  
Affidavit of Robert Parker Blackburn (11/1/95)

**[Volume 12]**

I.A.130. Murex Reply in the Litigation of Chiron Australian Patent No. 624,105, which includes:

Affidavit of Baruch S. Blumberg (3/14/96)  
Affidavit of Patrick Robert Carnegie (3/25/96)  
Affidavit of Lynn Dalgarno (3/28/96)  
Affidavit of Eric James Gowans (3/24/96)  
Affidavit of David James Kemp (3/1/96)  
Affidavit of Stephen Alister Locarnini (3/1/96)  
Affidavit of Gregory R. Reyes (3/15/96)  
Affidavit of Daniel W. Bradley (3/9/96)  
Affidavit of Simon Joshua Leach (3/13/96)  
Affidavit of John Nicholas Crofts (3/1/96)  
Affidavit of Peter Simmonds (3/18/96)

**[Volume 13]**

I.A.131. European Patent Application 0293274  
I.A.132. PCT Patent Application WO 89/10967  
I.A.133. First Opposition to Chiron European Application No. 0 318 216, filed by Akzo Pharma BV (01/27/94) with supporting documents including:  
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- I.A.134. Second Opposition to Chiron European Application No. 0 318 216, filed by Murex Diagnostics Limited(09/12/94) with supporting documents including:  
General list of references used by the six opponents to EP 318 216 with attached list of Murex references
- I.A.135. Third Opposition to Chiron European Application No. 0 318 216, filed by United Biomedical (09/15/94) with supporting documents including:  
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- I.A.136. Fourth Opposition to Chiron European Application No. 0 318 216, filed by Beringwerke (09/15/94)
- I.A.137. Fifth Opposition to Chiron European Application No. 0 318 216, filed by The Research Foundation for Microbial Diseases (09/14/94) with supporting documents including:  
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- I.A.138. Sixth Opposition to Chiron European Application No. 0 318 216, filed by F. Hoffman-La Roche AG(09/15/94):
- I.A.139. J.A. Kemp & Co.(Chiron): Response By Patentee To Notices of Opposition re EP 318 216, June 1995

**[Volume 14]**

- I.A.140. Miscellaneous Documentation (believed to have been supplied to Prof. Donald Chisum by Dr. Bradley or the Center for Disease Control)

**[Volume 15]**

- I.A.141. Daniel W. Bradley v. Chiron Corporation, Civil Action No. 94-4342 Litigation Bundle, which includes:  
Defendants' Memorandum in Support of Their Motion to Dismiss the Complaint, filed in the Northern District of California on March 6, 1995  
Plaintiff's Memo in Opposition to the Chiron Defendants' Motion to Dismiss, filed in the Northern District of California on May 19, 1995  
Order Granting Defendant's Motion to Dismiss and Granting Leave to Amend, filed in the Northern District of California on November 15, 1995

Second Amended Complaint of Daniel W. Bradley against Chiron Corporation, et al., filed in the Northern District of California on December 20, 1994, (with Exhibits A through WW)

**[Volume 16]**

Defendants' Motion and Memorandum in Support of Their Motion to Dismiss the Second Amended Complaint and to Strike Certain Claims and Allegations, filed in the Northern District of California on February 7, 1996

Plaintiff's Memorandum in Opposition to Defendants' Motion to Dismiss and to Strike Certain Allegations in His Second Amended Complaint, filed in the Northern District of California on April 5, 1996

- I.A.142. European Patent Application 0442394 A2
- I.A.143. United States Patent 5,106,726
- I.A.144. United States Patent 5,436,126
- I.A.145. European Patent Application 0468527 A2

[The following material relating to the litigation of Chiron U.K. patent No. 2,212,511 was previously submitted to the U.S. Patent office in the Information Disclosure Statement filed December 15, 1993 for application serial no. 08/103,961. Applicants provided this information to the U.S. Patent office as requested during an the interview with Examiner Sisson on the 08/103,961 application. This information was reviewed by Examiner Sisson, although not formally made of record on a PTO 1449 in the '961 application. On December 21, 1994, Examiner Sission issued an Examiner Interview Summary Record, Paper No. 23 in the '961 file, stating that the U.K. litigation materials associated with the Information Disclosure Statement received 12/16/93 had been considered on the merits. Applicants are, herewith, submitting a PTO 1449 covering this U.K. litigation materials for the present application but are not submitting copies pursuant to 37 C.F.R. § 1.98(d).]

- I.A.146. [U.K. LITIGATION Bundle 1] , which includes:

The Patent In Suit, UK Patent 2,212,511 for HEPATITIS C VIRUS (Houghton, et al.), patent published 1/22/92. (previously provided to the Patent office in US 08/103,961, reference III.A.1)

- I.A.147. [U.K. LITIGATION Bundle 2], which includes:

Amended Writ (Chiron Corp., et al. v. Organon Teknika, Ltd., et al. CH 1992 C No. 489) (previously provided to the Patent office in US 08/103,961, reference III.A.2)

Original Writ (Chiron Corp., et al. v. BCW Operations Ltd., CH 1992 C No. 1513) (previously provided to the Patent office in US 08/103,961, reference III.A.3)



Re-Amended Statement of Claim (Chiron Corp., et al. v. Organon Teknika Ltd., et al., CH 1992 C No. 489) (previously provided to the Patent office in US 08/103,961, reference III.A.4)

Amended Statement of Claim (Chiron Corp., et al. v. Murex Diagnostics Ltd., CH 1992 C No. 1513) (previously provided to the Patent office in US 08/103,961, reference III.A.5)

Amended Particulars of Infringement (Chiron Corp., et al. v. Organon Teknika Ltd., CH 1992 C No. 489)(previously provided to the Patent office in US 08/103,961, reference III.A.6)

Particulars of Infringement (Chiron Corp., et al. v. BCW Operations Ltd., CH 1992 C No. 1513) (previously provided to the Patent office in US 08/103,961, reference III.A.7)

Amended Defense and Counterclaim of the Fifth Defendant (Chiron Corp., et al. v. Organon Teknika Ltd., et al., CH 1992 C No. 489) (previously provided to the Patent office in US 08/103,961, reference III.A.8)

Re-Re-Re-Amended Particulars of Objections of the Fifth Defendant (Chiron Corp., et al., v. Organon Teknika Ltd., et al., CH 1992 C No. 489) (previously provided to the Patent office in US 08/103,961, reference III.A.9)

Amended Voluntary and Better Particulars of Insufficiency of Disclosure an Extension of Disclosure Under Particulars of Objections of the Fifth Defendant (Chiron Corp., et al. v. Organon Teknika Ltd., et al., CH 1992 C No. 489) (previously provided to the Patent office in US 08/103,961, reference III.A.10)

Amended Reply and Defense to Counterclaim of the Fifth Defendant (Chiron Corp., et al. v. Organon Teknika Ltd., et al. CH 1992 C No. 489) (previously provided to the Patent office in US 08/103,961, reference III.A.11)

Further and Better Particulars of the Amended and Re-Amended Replies and of the Amended Answer (Chiron Corp., et al. v. Organon Teknika Ltd., et al. and Murex Diagnostics Ltd., Consolidated Actions No. CH 1992 C No. 489, CH 1992 C No. 1513 and CH 1992 B No. 5552) (previously provided to the Patent office in US 08/103,961, reference III.A.12)

Notice Pursuant to the Civil Evidence Act 1968 and RSC Order 38, Rules 21 to 25 (Chiron Corp., et al. v. Organon Teknika Ltd., et al. and Murex Diagnostics Ltd., Consolidated Actions No. CH 1992 C

No. 489, and CH 1992 C No. 1513) (previously provided to the Patent office in US 08/103,961, reference III.A.13)

Notice of Motion (Chiron Corp., et al. v. Organon Teknika Ltd., et al., CH 1992 C No. 489, 6/4/93) (previously provided to the Patent office in US 08/103,961, reference III.A.14)

Notice of Motion (Chiron Corp., et al. v. Organon Teknika Ltd., et al., CH 1992 C No. 489, 6/28/93) (previously provided to the Patent office in US 08/103,961, reference III.A.15)

Consolidated Defense and Counterclaim of all Defendants (Chiron Corp., et al. v. Organon Teknika Ltd., et al. and Murex Diagnostics Ltd., Consolidated Actions No. CH 1992 C No. 489, and CH 1992 C No. 1513) (previously provided to the Patent office in US 08/103,961, reference III.A.16)

Consolidated Particulars of Objections of all Defendants (Chiron Corp., et al. v. Organon Teknika Ltd., et al. and Murex Diagnostics Ltd., Consolidated Actions No. CH 1992 C No. 489, and CH 1992 C No. 1513) (previously provided to the Patent office in US 08/103,961, reference III.A.17)

Amended Notice Under Section 2 of the Civil Evidence Act 1968 (Chiron Corp., et al. v. Organon Teknika Ltd., et al. CH 1992 C No. 489) (previously provided to the Patent office in US 08/103,961, reference III.A.18)

Notice of Motion (Chiron Corp., et al. v. Organon Teknika Ltd., et al. and Murex Diagnostics Ltd., Consolidated Actions No. CH 1992 C No. 489, and CH 1992 C No. 1513, 6/30/93) (previously provided to the Patent office in US 08/103,961, reference III.A.19)

Notice of Motion (Chiron Corp., et al. v. Murex Diagnostics Ltd., CH 1992 C No. 1513, 4/8/93) (previously provided to the Patent office in US 08/103,961, reference III.A.20)

Notice of Motion (Chiron Corp., et al. v. Organon Teknika Ltd., et al., CH 1992 C No. 489, 4/8/93) (previously provided to the Patent office in US 08/103,961, reference III.A.21)

Affidavit of Gregor McIntyre Grant (Chiron Corp., et al. v. Murex Diagnostics Ltd., CH 1992 C No. 1513) (previously provided to the Patent office in US 08/103,961, reference III.A.22)

Fifth Affidavit of Christopher Peter Tootal (Chiron Corp., et al. v. Organon Teknika Ltd., et al. and Murex Diagnostics Ltd., Consolidated Actions No. CH 1992 C No. 489, and CH 1992 C

No. 1513) (previously provided to the Patent office in US 08/103,961, reference III.A.23)

Affidavit of Laura A. Coruzzi filed 13 February 1992 with the High Court of Justice Chancery Division Patents Court, Case No. 489, Chiron Corp., Ortho Diagnostic Systems, Inc. and Ortho Diagnostic Systems Limited v. Organon Teknika Ltd.; (previously considered in US 07/456,637, reference FFK) (previously provided to the Patent office in US 08/103,961, reference III.A.24)

Affidavit of Professor Sir Aaron Klug, ScD, Hon FRCP, FRS, filed 13 February 1992 with the High Court of Justice Chancery Division Patents Court, Case No. 489, Chiron Corp., Ortho Diagnostic Systems, Inc. and Ortho Diagnostic Systems Limited v. Organon Teknika Ltd. (previously considered in US 07/456,637, reference FFL) (previously provided to the Patent office in US 08/103,961, reference III.A.25)

I.A.148. [U.K. LITIGATION Bundle 5], which includes:

Witness Statement of Michael Houghton;

Witness Statement of Amy Joan Weiner

Witness Statement of George Kuo

Witness Statement of Michael Joseph McGarvey

Affidavit of Robert Tjian

Supplemental Witness Statement of Amy Joan Weiner

I.A.149. [U.K. LITIGATION Bundle 6], which includes:

Expert's Report of William J. Brammar

Expert's Report of Howard Christopher Thomas

Experts Report of Harold Eliot Varmus

Supplemental Expert's Report of William J. Brammar

Supplemental Expert's Report of Howard Christopher Thomas

I.A.150. [U.K. LITIGATION Bundle 7], which includes:

Annexure 1 to the Witness Statement of Michael Houghton—Michael Houghton CV

Annexure AJW-1 to Witness Statement of Amy Joan Weiner—New York Times 5/11/88

Annexure GK-1 to the Witness Statement of George Kuo—George Kuo CV

Annexure GK-2 to the Witness Statement of George Kuo—Quote regarding "snarks"

Annexure MJM-1 to Witness Statement of Michael Joseph McGarvey—McGarvey, et al., Proc. Natl. Acad. Sci. USA **81**:3690 (1984)

Annexure MJM-2 to Witness Statement of Michael Joseph McGarvey—Award to McGarvey from the Nuffield Foundation

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Annexure 8 to Witness Statement of William J. Brammar—Fig. 14-1, combined ORF of DNAs

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Annexure HCT-1 to Witness Statement of Howard Christopher Thomas—Howard Christopher Thomas CV

Annexure HCT-2 to Witness Statement of Howard Christopher Thomas—Historical listing of references over time to specific issues

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Annexure 15 to Supplemental Expert's Report of William J. Brammar—Homology with the RRV-decapptides

Annexure 16 to Supplemental Expert's Report of William J. Brammar—Lab result printouts

Annexure 17 to Supplemental Expert's Report of William J. Brammar—Alignment between the hypothetical peptide translated from one of the reading frames of the cDNA sequence from Fig. 2b of the Arima European Patent and the N-terminus of the HCV polyprotein

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Annexure AJW-6 to Witness Statement of Amy Joan Weiner—Description of Fig. 4

Annexure AJW-7 to Witness Statement of Amy Joan Weiner—Overhead from Oral Presentation

Annexure AJW-8 to Witness Statement of Amy Joan Weiner—Lab Notebook pages from Book 5547

Annexure AJW-9 to Witness Statement of Amy Joan Weiner—Amy Weiner CV

I.A.154. [U.K. LITIGATION Bundle 8 ], which includes:  
Expert Report of Professor J.W. Almond



Expert Report of Dr. Timothy John Harrison  
Expert's Report - Dr. Nicholas Clwyd Jones  
Witness Statement of Professor Sir Aaron Klug  
Witness Statement of Professor Baruch S. Blumberg  
Statement of Dr. Gregory R. Reyes  
Witness Statement - Professor Terukatsu Arima  
First Affidavit of Dr. John Gregory Aaskov  
Statement by Michael J. Evans  
Supplementary Expert Report of Professor J.W. Almond  
Witness Statement of Dr. Jan Albert Hellings  
Witness Statement of Peter Edmund Highfield  
Statement of Dr. Daniel Caput  
Statement of Dr. Barbara Hosein  
Statement of Jeffrey William Almond  
Witness Statement of Dr. Elizabeth Ann Fagan

- I.A.155. [U.K. LITIGATION Bundle 9], which includes:
- Annex 1 through 4 to the Witness Statement of Dr. Almond
  - Appendix 1 through 4 to the Expert Report of Dr. Harrison
  - Annex A through C to Witness Statement of Dr. Jones
  - Exhibit NJC-1 to Second Witness Statement of Dr. Jones
  - Exhibit AK-1 to Statement of Professor Klug
  - Exhibit AK-2 to Statement of Professor Klug—Goedert, et al., Proc. Natl. Acad. Sci. USA **85**:4051 (1988)
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- I.A.158. [UK Interlocutory Affidavits and Exhibits, Vol. 1], which includes:  
Affidavit of Ian Armitage—(with Exhibits)  
Affidavit of Professor Baruch Samuel Blumberg—(with Exhibits)  
Affidavit of Laura A. Coruzzi—(with Exhibits)
- I.A.159. [UK Interlocutory Affidavits and Exhibits, Vol. 2], which includes:  
Affidavit of Douglas Michael Goldin—(with Exhibits)
- I.A.160. [UK Interlocutory Affidavits and Exhibits, Vol. 3], which includes:  
Affidavit of Professor Sir Aaron Klug, ScD, Hon FRCP,  
FRS—(with Exhibit)  
Affidavit of William J. Rutter—(with Exhibits)  
Affidavit of Dame Shiela Patricia Violet Sherlock—(with Exhibits)  
Affidavit of Martha Ann Truett—(with Exhibits)
- I.A.161. [UK Interlocutory Affidavits and Exhibits, Vol. 4], which includes:  
Affidavit of Douglas Michael Goldin—(with Exhibits)  
Affidavit of Peter Edmund Highfield—(with Exhibits)  
Affidavit of Judith Silveston—(with Exhibits)  
Affidavit of Richard Seton Tedder—(with Exhibits)
- I.A.162. [UK Transcript Speeches and Evidence, Vol. 4], which includes:  
UK Trial Transcript Speeches: Volume S1-S7, Monday July 5,  
1993 through Monday, August 2, 1993  
UK Trial Transcript Evidence: Volume E1-E15, Tuesday July 6,  
1993 through Monday July 26, 1993

Witness statements and testimony (examination and cross-examination) of Drs. Houghton, Kuo, Weiner, McGarvey, Reyes and Caput

The Expert reports and testimony (examination and cross-examination) of Drs. Brammar, Thomas, Varmus, Almond, Harrison, Jones, Klug and Blumberg

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- I.B.3. Viral Hepatitis and Liver Disease 620 (1984); (previously considered in US 08/103,961, reference I.A.90)
- I.B.4. Winnacker, "From Genes to Clones Introduction to Gene Technology," (publ., VCH Germany, 1987), pp. 39-41; (previously considered in US 08/103,961, reference V.20)
- I.B.5. Aaskov, et al., "An Immunofluorescence Assay for Human Antibodies to Ross River Virus," J. Immu. Meth. 25:37-41 (1979); (previously considered in US 08/103,961, reference I.A.2)
- I.B.6. Akatsuka, et al., (Eisai KK), "Non-A, Non-B Hepatitis-associated monoclonal antibody and diagnostic agent," JP 183629/1983; (previously considered in US 08/103,961, reference I.A.4)
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- I.B.142. Chiron Laboratory Notebook #1298, pp. 184-190, 192 (November, 1986); (previously considered in US 08/103,961, reference I.A.117)
- I.B.143. Memorandum by Dr. Houghton, dated November 10, 1987; (previously considered in US 08/103,961, reference I.A.118)
- I.B.144. Inventorship Opinion of Gladys Monroy dated June 7, 1988; (previously considered in US 08/103,961, reference I.A.119)
- I.B.145. Letter dated October 16, 1989 from Mr. Lanman of the NIH to Robert Blackburn of Chiron Corporation

- I.B.146. Bradley, et al., Prog. Med. Virol. **37**:101-135 (1990) (cited by the examiner in 07/456,637, paper 23; and 08/103,961, reference I.B.61)
- I.B.147. Weiner, et al., J. Virol. **62(2)**:594-599 (1988); (previously considered in US 07/122,174, 07/139,886, 07/161,072, 07/191,263; and US 08/103,961, reference I.B.354)
- I.B.148. Choo, et al., Genetics, Organization and diversity of the Hepatitis C virus," Proc. Natl. Acad. Sci. USA **88**:1-5 (1991); (previously considered in US/456,637, reference I.B.83)
- I.B.149. Proc. Japan Acad., **65**,ser.V. No.9, pp.219-223 (1989)
- I.B.150. Taiwan Patent Application No. 77108060 (Houghton, et al., subject to Taiwan Opposition 1)
- I.B.151. Methods in Enzymology vol. 155, part F (1987) (previously considered in US 08/103,961, reference I.A.12)
- I.B.152. Bradley, "Non-A/Non-B Hepatitis in Experimentally Infected Chimpanzees: Cross Challenge and Electron Microscopic Studies," J Med Virol **6**:185-201 (1980); (previously considered in US 07/456,637, reference I.B.57)
- I.B.153. Houghton, et al. (Chiron Corporation), "Hepatitis C Virus," UK Patent 2,212,511 (1/22/92); (previously considered in US 08/103,961, reference I.A.46)
- I.B.154. Dialog Computer Printout (previously considered in US 08/103,961, reference V.3)
- I.B.155. Alter, "Transfusion-Associated Non-A, Non-B Hepatitis: The First Decade," Viral Hepatitis and Liver Disease, (Zuckermann, Ed.) p.537; (Considered in US 08/103,961, reference I.A.3)
- I.B.156. Arima, et al., "Cloning of Serum RNA Associated with Hepatitis C Infection Suggesting Heterogeneity of the Agent(s) Responsible for Infection," Chemical Abstract, **112(11)**:441 (1990); (Considered in US 08/103,961, reference I.A.6)
- I.B.157. Arima, "Cloning of a cDNA Associated with Acute and Chronic Hepatitis C Infection Generated from Patients Serum RNA," Chem. Abstract, **112(1)**:209 (1990); (Considered in US 08/103,961, reference I.A.7)
- I.B.158. Arima, "A Lambda gt11-cDNA Clone Specific for Chronic Hepatitis C Generated from Pooled Serum Presumably Infected by Hepatitis C Virus," Chem. Abstract, **112(7)**:169 (1990); (Considered in US 08/103,961, reference I.A.8)

- I.B.159. Boender, et al., "Fragmented Chromosomal DNA in Sera of Patients with Hepatitis A, B, and Non-A, Non-B," Viral Hepatitis and Liver Disease (Zuckerman, ed.) pp. 588-591 (1988); (Considered in US 08/103,961, reference I.A.13)
- I.B.160. Bradley, et al., "Non-A, Non-B Hepatitis in Experimentally Infected Chimpanzees: Comparative Morphology of Virus-Induced Ultrastructural Changes," Hepatitis Viruses and Hepatocellular Carcinoma, pp. 226-260 (1985); (Considered in US 08/103,961, reference I.A.14)
- I.B.161. Brotman, et al., "Interference Between Non-A, Non-B and Hepatitis B Virus Infection in Chimpanzees," J. Med. Vir., **11**:191-205 (1983); (Considered in US 08/103,961, reference I.A.20)
- I.B.162. Arima, et al., US Patent 5,191,064; (Considered in US 08/103,961, reference I.A.102)
- I.B.163. Reyes, et al., US Patent 5,218,099; (Considered in US 08/103,961, reference I.A.104)
- I.B.164. Neurath, et al., "An Antigen Detected Frequently in Human Sera with Elevated Levels of Alanine Aminotransferase: A Potential Marker for Non-A, Non-B Hepatitis," J. Gen. Virol., **48**:285-295 (1980); (Considered in US 07/456,637, reference SQ; and US 08/103,961, reference I.B.220)
- I.B.165. Shimizu, et al., "Production of Antibody Associated with Non-A, Non-B Hepatitis In A Chimpanzee Lymphoblastoid Cell Line Established by in vitro Transformation with Epstein-Barr Virus," Proc. Natl. Acad. Sci. USA, **82**:2138-2142 (1985); (Considered in US 07/456,637, reference HL; and US 08/103,961, reference I.B.280)
- I.B.166. Shimizu, et al., "Further Studies by Immunofluorescence of the Monoclonal Antibodies Associated with Experimental Non-A, Non-B Hepatitis in Chimpanzees and Their Relation to Delta Hepatitis," Hepatology, **6**:1329-1333 (1986); (Considered in US 07/456,637, reference HN; and US 08/103,961, reference I.B.278)
- I.B.167. Prince, et al., "Isolation of a Virus from Chimpanzee Liver Cell Cultures Inoculated with Sera Containing the Agent of Non-A, Non-B Hepatitis," The Lancet, 10 November 1984, pp. 1071-1075; (Considered in US 07/456,637, reference DO; and US 08/103,961, reference I.B.248)

- I.B.168. Arima, et al., "Serum RNA Associated with Blood-Transmitted Non-A, Non-B Hepatitis," Hepatology, **8**:1275 (1988); (Considered in US 07/456,637, reference CCO; and US 08/103,961, reference I.B.34)
- I.B.169. Arima, et al., "Cloning of Serum RNA Associated with Hepatitis C Infection Suggesting Heterogeneity of the Agent(s) Responsible for Infection," Gastroenterol. Jpn., **25(6)**:685-691 (1989); (Considered in US 07/456,637, reference IM; and US 08/103,961, reference I.B.32)
- I.B.170. Bradley, et al., "Non-A, Non-B Hepatitis in Experimentally Infected Chimpanzees: Comparative Morphology of Virus-Induced Ultrastructural Changes," Academic Press Japan, (1985); (Considered in US 07/456,637, reference EEN; and US 08/103,961, reference I.B.47)
- I.B.171. Bradley, et al., "Non-A, Non-B Hepatitis: Research Progress and Current Perspectives," Dev. Biol. Standard, **54**:63-73 (1983); (Considered in US 07/456,637, reference EEM; and US 08/103,961, reference I.B.49)
- I.B.172. Bradley, et al., "Parenterally Transmitted Non-A, Non-B Hepatitis Virus-Specific Antibody Response Patters in Hepatitis C Virus-Infected Chimpanzees," Gastroenterology, **99**:1054-1060 (1990); (Considered in US 07/456,637, reference LM; and US 08/103,961, reference I.B.50)
- I.B.173. Bradley, et al., "Transmission of Non-A, Non-B Hepatitis to Chimpanzees: Recovery of Virus-Like Particles," Abstr. Ann. Mtg. Am. Soc. Microbiol., **79**:267 (1979); (Considered in US 07/456,637, reference QQ; and US 08/103,961, reference I.B.46)
- I.B.174. Bradley, et al., "Aetiological Agent of Enterically Transmitted Non-A, Non-B Hepatitis," J. Gen. Virol., **69**:731-738 (1988); (Considered in US 07/456,637, reference CCP; and US 08/103,961, reference I.B.52)
- I.B.175. Bradley, et al., "Non-A, Non-B Hepatitis in Chimpanzees: Interference with Acute Hepatitis A Virus and Chronic Hepatitis B Virus Infections," J. Med. Virol., **11**:207-213 (1983); (Considered in US 07/456,637, reference GR; and US 08/103,961, reference I.B.53)
- I.B.176. Bradley, et al., "Persistent Non-A, Non-B Hepatitis in Experimentally Infected Chimpanzees," J. Infect. Dis., **143**:210-218 (1981); (Considered in US 07/456,637, reference EEK; and US 08/103,961, reference I.B.54)

- I.B.177. Bradley, et al., "Viroids and Viral Hepatitis in Marmosets," Nature, **248**:172 (1974); (Considered in US 07/456,637, reference PT; and US 08/103,961, reference I.B.58)
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- I.B.179. Bradley, et al., "Virus of Enterically Transmitted Non-A, Non-B Hepatitis," The Lancet, 9 April 1988, p. 819; (Considered in US 07/456,637, reference CCQ; and US 08/103,961, reference I.B.63)
- I.B.180. Brotman, et al., "Non-A, Non-B Hepatitis: Is There More Than A Single Blood-Borne Strain?," J. Infect. Dis., **151**:618-625 (1985); (Considered in US 07/456,637, reference DP; and US 08/103,961, reference I.B.65)
- I.B.181. Dienstag, "Non-A, Non-B Hepatitis I Recognition, Epidemiology and Clinical Features," Gastroenterology, **85**:439-462 (1983); (Considered in US 07/456,637, reference AO; and US 08/103,961, reference I.B.104)
- I.B.182. Dienstag, "Non-A, Non-B Hepatitis II Experimental Transmission, Putative Virus Agents and Markers, and Prevention," Gastroenterology, **85**:743-768 (1983); (Considered in US 07/456,637, reference AP; and US 08/103,961, reference I.B.105)
- I.B.183. Hallam, "Non-A, Non-B Hepatitis: Reverse Transcriptase Activity?," The Lancet, 21 September 1985, p. 665; (Considered in US 07/456,637, reference EP; and US 08/103,961, reference I.B.148)
- I.B.184. Itoh, et al., "Lack of Detectable Reverse-Transcriptase Activity in Human and Chimpanzee Sera with a High Infectivity for Non-A, Non-B Hepatitis," J. Gen. Virol., **67**:777 (1986); (Considered in US 07/456,637, reference ES; and US 08/103,961, reference I.B.167)
- I.B.185. Linke, et al., "Non-A, Non-B Hepatitis Infection Does Not Result in the Production of Abundant Poly-A-Containing Messenger RNAs," Viral Hepatitis and Liver Disease (Zuckerman, ed.) pp.564-567 (1988); (Considered in US 08/103,961, reference I.A.55)
- I.B.186. Alter, "Transfusion-Associated Non-A, Non-B Hepatitis: The First Decade," J. Med. Virol., **21**:43A (1987); (Considered in US 07/456,637, reference BBQ; and US 08/103,961, reference I.B.22)

- I.B.187. Alter, et al., "Non-A, Non-B Hepatitis: Its Relationship to Cytomegalovirus, to Chronic Hepatitis and to Direct and Indirect Test Methods," Viral Hepatitis, 1981 Int'l Symposium, pp. 279-294 (1981); (Considered in US 07/456,637, reference GO; and US 08/103,961, reference I.B.26)
- I.B.188. Feinstone, et al., "Non-A, Maybe-B Hepatitis," New England J. Med., **311(3)**:185-189 (1973); (Considered in US 08/103,961, reference I.A.37)
- I.B.189. Fraenkel-Conrat, et al. (ed.), The Viruses: The Togaviridae and Flaviviridae (1986), Plenum Press); (Considered in US 08/103,961, reference I.A.39)
- I.B.190. Hellings, et al., "Transmission of Non-A, Non-B Hepatitis by Leucocyte Preparations," Viral Hepatitis and Liver Disease (Zuckerman, ed.), pp. 543-549 (1988); (Considered in US 08/103,961, reference I.A.43)
- I.B.191. Alter, et al., "Non-A, Non-B: Observations on the First Decade," Viral Hepatitis and Liver Disease (Vyas, et al. eds.) pp. 345-354 (1984); (Considered in US 07/456,637, reference PO; and US 08/103,961, reference I.B.25)
- I.B.192. Charney, et al., "Analysis by Hybridization with HBV DNA of Hepatocellular DNA from Patients with Chronic Non-A, Non-B Hepatitis," Viral Hepatitis: 1981 International Symposium (Szmuness, et al., eds. (pp. 656-657) 1985, Franklin Institute Press); (Considered in US 08/103,961, reference I.A.27)

## **II. INFORMATION PERTAINING TO THE INVENTORSHIP OF THE APPLICATION**

In the Information Disclosure Statement filed December 27, 1991 in parent application Serial No. 07/456,637 (as well as in the interview held on January 9, 1992), Applicants' called to the Examiner's attention to the fact that Dr. Daniel Bradley formerly of the Centers for Disease Control (CDC) had made a claim to be a co-inventor of the invention which constituted the initial cloning of HCV and the development of immunoassays for anti-HCV antibodies employing HCV antigens generally. Applicants previously provided a substantial amount of this material in the parent applications 07/103,961 and 08/103,961. Applicants' request that the



Examiner consider and make of record in the present application the following listed information.

Dr. Daniel Bradley's claim to inventorship of the present invention has been previously brought to the attention of the United States Patent and Trademark office. Dr. Bradley has now initiated litigation against the applicants and the assignee of this application alleging, inter alia, misjoinder of inventorship and that the PTO has not considered his allegations. Applicants have previously submitted articles by Dr. Bradley summarizing his position, as well as an independent legal opinion by Professor Donald Chisum, Esq. on the subject of Dr. Bradley's claim to inventorship. Professor Chisum rendered his opinion after conducting a thorough independent investigation, including interviewing Dr. Bradley at the CDC.

Further to the information disclosed previously, applicants are submitting herewith the pleadings filed in the above-mentioned litigation. The Examiner may wish to note that in the Second Amended Complaint (I.A. 141), Dr. Bradley admits that the view of CDC's lawyer was that his claim to coinventorship was not viable. See page 71, line 11 of the Second Amended complaint. In addition, applicants are submitting miscellaneous documents that they believe may have been provided by either Dr. Bradley or the CDC, his employer at the time, during the course of Professor Chisum's inventorship investigation. Further, it is believed by applicants that no explanation of the relevance of any of these documents, e.g., date, authorship, etc. has ever been provided to assignee or applicants. The Examiner should also refer to Dr. Bradley's evidence in the Australian litigation with Murex, I.A. 129 and I.A. 130. Drs. Houghton's, Kuo's and Weiner's evidence therein should also be considered.

The following information was previously submitted to the Examiner with the December 1991 IDS in the 07/456,637 application and the December 1993 IDS of the 08/103,961 application:

- II.A.1. Letter dated October 16, 1989, from Mr. Lanman at the NIH to Robert Blackburn at Chiron; (previously considered in US 08/103,961, reference I.A.106; cited above as I.B.131)
- II.A.2. Opinion of Professor Donald Chisum June 1991; (previously considered in US 08/103,961, reference I.A.107; cited above as I.B.132)

- II.A.3. "Agreement of Settlement" dated April 3, 1990 between Chiron Corporation and the Centers for Disease Control; (previously considered in US 08/103,961, reference I.A.108; cited above as I.B.133)
- II.A.4. "Independent Legal Opinion Concerning Hepatitis C Inventorship Dispute", June 1991; (previously considered in US 08/103,961, reference I.A.109; cited above as I.B.134)
- II.A.5. Memorandum Re Interviews of Dr. Qui-Lim Choo and Dr. George Kuo dated May 8, 1991; (previously considered in US 08/103,961, reference I.A.110; cited above as I.B.135)
- II.A.6. Memorandum Re Interview of Dr. Michael Houghton dated May 8, 1991; (previously considered in US 08/103,961, reference I.A.111; cited above as I.B.136)
- II.A.7. Memorandum Re Interview of Dr. Daniel Bradley dated April 11, 1991; (previously considered in US 08/103,961, reference I.A.112; cited above as I.B.137)
- II.A.8. Memorandum Re Interviews of Dr. Amy Weiner and Dr. Gary Van Nest dated April 30, 1993; (previously considered in US 08/103,961, reference I.A.113; cited above as I.B.138)
- II.A.9. Memorandum Re Interview of Dr. Lacy Overby dated June 21, 1991; (previously considered in US 08/103,961, reference I.A.114; cited above as I.B.139)
- II.A.10. Memorandum dated November 11, 1987 by Dr. Michael Houghton; (previously considered in US 08/103,961, reference I.A.115; cited above as I.B.140)
- II.A.11. Memorandum by Dr. Michael Houghton (undated); (previously considered in US 08/103,961, reference I.A.116; cited above as I.B.141)
- II.A.12. Chiron Laboratory Notebook #1298, pp. 184-190, 192 (November, 1986); (previously considered in US 08/103,961, reference I.A.117; cited above as I.B.142)
- II.A.13. Memorandum by Dr. Houghton, dated November 10, 1987; (previously considered in US 08/103,961, reference I.A.118; cited above as I.B.143)
- II.A.14. Inventorship Opinion of Gladys Monroy dated June 7, 1988; (previously considered in US 08/103,961, reference I.A.119; cited above as I.B.144)

- II.A.15. Letter dated October 16, 1989 from Mr. Lanman of the NIH to Robert Blackburn of Chiron Corporation (cited above as I.B.145)
- II.A.16. Bradley, et al., Prog. Med. Virol. **37**:101-135 (1990) (cited by the examiner in 07/456,637, paper 23; and 08/103,961, reference I.B.61; cited above as I.B.146)

[At the time the opinion was prepared, the patent attorneys responsible for prosecuting the ancestors of the present application were not associated with Morrison & Foerster, who were hired to provide an independent assessment of inventorship. The undersigned was with the firm of Irell & Manella, who were acting as Chiron's outside patent counsel in the ancestor applications. It was not until September 1991 that the patent group in Irell & Manella's Menlo Park, California office, the undersigned included, joined Morrison & Foerster.]

In addition to the above information, Applicants submit the following supplementary information relating to inventorship with this Information Disclosure Statement:

- II.A.17. Bradley Miscellaneous Documentation (believed to have been supplied by Dr. Bradley or the Center for Disease Control) (cited above in I.A.)
- II.A.18. Daniel W. Bradley v. Chiron Corporation, Civil Action No. 94-4342 Litigation Bundle, which includes:
  - Defendants' Memorandum in Support of Their Motion to Dismiss the Complaint, filed in the Northern District of California on March 6, 1995
  - Plaintiff's Memo in Opposition to the Chiron Defendants' Motion to Dismiss, filed in the Northern District of California on May 19, 1995
  - Order Granting Defendant's Motion to Dismiss and Granting Leave to Amend, filed in the Northern District of California on November 15, 1995
  - Second Amended Complaint of Daniel W. Bradley against Chiron Corporation, et al., filed in the Northern District of California on December 20, 1994, (with Exhibits A through WW)
  - Defendants' Motion and Memorandum in Support of Their Motion to Dismiss the Second Amended Complaint and to Strike Certain Claims and Allegations, filed in the Northern District of California on February 7, 1996

Plaintiff's Memorandum in Opposition to Defendants' Motion to Dismiss and to Strike Certain Allegations in His Second Amended Complaint, filed in the Northern District of California on April 5, 1996

There are, of course, many other documents relating to the project that led to the cloning of HCV. Applicants offer to make non-privileged portions of this material available to the Examiner and will consider the disclosure of privileged materials based, inter alia, on the nature of the material and the request, as well as the availability of any material information from a non-privileged source.

**III. REFERENCES AND OTHER MATERIALS CITED TOWARDS REJECTIONS OF CLAIMS OR OBJECTIONS TO THE SPECIFICATION CORRESPONDING TO THE FIRST FOREIGN FILING**

The documents in the list below have been cited in a rejection of claims or an objection to the specification of one of the following U.S. Patent Applications or a corresponding foreign patent application or issued patent claiming priority from one of the following U.S. Patent Applications, whether in prosecution, litigation, opposition, or third party observations: U.S. Applications 07/122,174 (filed November 18, 1987), 07/139,886 (filed December 30, 1987), 07/161,072 (filed February 26, 1988), 07/191,263 (filed May 6, 1988), 07/263,584 (filed October 26, 1988), and 07/271,450 (filed November 14, 1988).

**III.A. List of Art Cited by a U.S. Examiner Against the Claims of a Parent Application**

III.A.1. Seto, et al., US Patent 4,673,634 (1987); (previously considered in US 07/122,174, US 07/139,886, US 07/161,072, US 07/191,263 (paper no. 5) and US 07/456,637, reference BA; cited above as I.B.102)

III.A.2. Villarejos, et al., US Patent 4,702,909 (1987); (previously considered in US 07/122,174, US 07/139,886, US 07/161,072, US 07/191,263 (paper no. 5), and US 07/456,637, reference BB; cited above as I.B.116)

**III.B. List of Art Cited Against the Claims During the Prosecution of AUSTRALIAN Patent No. 624,105**

[This information was cited during prosecution of the AUSTRALIAN application which claims priority from US Application Nos. 07/122,174, 07/139,886, 07/161,072, 07/191,263, 07/263,584, and 07/271,450]

- III.B.1. Shirachi, et al., The Lancet 8095:853-856 (1978) (previously considered in US 07/456,637, reference OO; and US 08/103,961, reference I.B.282; cited above as I.B.106)
- III.B.2. Wang, et al., Nature 323:508-513 (1986) (previously considered in US 07/191,263 (paper no. 5) and US 07/456,637, reference OM; and US 08/103,961, reference I.B.345; cited above as I.B.119)
- III.C. List of References Cited in the Litigation of AUSTRALIAN Patent No. 624,105
  - III.C.1. Amended Particulars of Invalidity (1995) in the Litigation of Australian Patent No. 624,105 (cited above in I.A.)
  - III.C.2. Application- with Statement of Claims and Particulars of Invalidity (03/03/94) in the Litigation of Australian Patent No. 624,105 (cited above in I.A.)
  - III.C.3. Particulars of Infringement (06/10/94) in the Litigation of Australian Patent No. 624,105 (cited above in I.A.)
  - III.C.4. Affidavit of Patrick Robert Carnegie (12/13/94) (cited above in I.A.)
  - III.C.5. Affidavit of Peter Malcolm Colman (12/15/94) (cited above in I.A.)
  - III.C.6. Affidavit of Eric James Gowans (12/15/94) (cited above in I.A.)
  - III.C.7. Affidavit of Lacy R. Overby (8/19/94) (cited above in I.A.)
  - III.C.8. Affidavit of Daniel W. Bradley (4/5/95) (cited above in I.A.)
  - III.C.9. Affidavit of George Kuo (10/23/95) (cited above in I.A.)
  - III.C.10. Affidavit of Robert Tjian (10/31/95) (cited above in I.A.)
  - III.C.11. Affidavit of Amy Joan Weiner (11/1/95) (cited above in I.A.)
  - III.C.12. Affidavit of Michael Steven Urdea (cited above in I.A.)
  - III.C.13. Affidavit of Michael Houghton (11/29/95) (cited above in I.A.)
- [Volume 9]
  - III.C.14. Affidavit of Gregory R.Reyes (12/05/94) (cited above in I.A.)
  - III.C.15. Affidavit of Stephen Alister Locarnini (12/08/94) (cited above in I.A.)
  - III.C.16. Affidavit of David James Kemp (12/07/94) (cited above in I.A.)
  - III.C.17. Affidavit of Ian David Gust (12/05/94) (cited above in I.A.)
  - III.C.18. Affidavit of Stephen M. Feinstone (08/11/94) (cited above in I.A.)
  - III.C.19. Affidavit of Lynn Dalgarno (12/08/94) (cited above in I.A.)

- III.C.20. Affidavit of Patrick Robert Carnegie (12/08/94) (cited above in I.A.)
- III.C.21. Affidavit of Baruch S. Blumberg (12/01/94) (cited above in I.A.)
- III.C.22. Affidavit of Terukatsu Arima (12/07/94) (cited above in I.A.)
- III.C.23. Affidavit of Peter Malcolm Colman (12/15/94) (cited above in I.A.)

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- III.C.24. Affidavit of Michael Joseph McGarvey (10/30/95) (cited above in I.A.)
- III.C.25. Affidavit of John Shine (12/04/95) (cited above in I.A.)
- III.C.26. Affidavit of Sir Gustav Nossal (12/12/95) (cited above in I.A.)
- III.C.27. Affidavit of John Mills (12/06/95) (cited above in I.A.)
- III.C.28. Affidavit of Robert William Beal (11/20/95) (cited above in I.A.)
- III.C.29. Affidavit of Gerald Wayne Both (11/24/95) (cited above in I.A.)
- III.C.30. Affidavit of Stephen R. Lee (10/24/95) (cited above in I.A.)
- III.C.31. Affidavit of Christopher John Burrell (11/20/95) (cited above in I.A.)
- III.C.32. Aaskov, et al., J. Immu. Meth. **25**:37-41 (1979); (previously considered in US 08/103,961, reference I.A.2; cited above at I.B.5)
- III.C.33. Arima et al., Gastroenterol. Jpn. **24**:540-544 (1989) (previously considered in US 07/456,637, reference IK; and US 08/103,961, reference I.B.33, cited above at I.B.10)
- III.C.34. Arima, et al., Gastroenterol. Jpn. **24(5)**:545-548 (1989); (previously considered in US 07/456,637, reference IL; and US 08/103,961, reference I.B.31; cited above as I.B.9)
- III.C.35. Backendorf, et al., Nucleic Acids Res. **14(7)**:2877- 2890 (1986); (previously considered in US 08/103,961, reference I.A.9, cited above at I.B.11)
- III.C.36. Bankier, et al., Mol. Biol. & Med. **1**:425-445 (1983) (previously considered in US 08/103,961, reference I.A.11; cited above as I.B.12)
- III.C.37. Mierendorf, et al., Methods in Enzymology, Ch. 51, 152, Berger & Kimmel (eds), Academic press Ltd. (1987) (previously considered in US 08/103,961, reference I.A.1) (cited above in I.A.)

- III.C.38. Bradley, Infection, Immunity and Blood Transfusion, Dodd, R. Y. & Barker, L.F. (eds.), Alan R. Liss Inc. 81-97 (1985) (cited above in I.A.)
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  - III.V.4. Table A showing the reactivity of the C-7 Antigen Region (cited above in I.A.)



- III.V.5. Table B showing the reactivities of C-5-1-1 and C100-3 (cited above in I.A.)
- III.V.6. Diagram schematically showing continuous epitopes and discontinuous epitopes (cited above in I.A.)
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III.Y. List of Art Cited in the Fourteenth Opposition against the JAPANESE Patent Application No. 01-500565

[This information was cited during the fourteenth opposition filed by F. Hoffman la Roche AG against the JAPANESE application which claims priority from U.S. Application Nos. 07/122,174, 07/139,886, 07/161,172, 01/191,263, 07/263,584 and 07/271,450]

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**IV. REFERENCES AND OTHER MATERIALS CITED TOWARDS A REJECTION OF THE CLAIMS OR OBJECTIONS TO THE SPECIFICATION CORRESPONDING TO THE SECOND FOREIGN FILING**

The documets in the list below have been cited in a rejection of claims or an objection to the specification of one of the following U.S. Patent Applications or a corresponding foreign patent application or issued patent claiming priority from one of the following U.S. Patent Applications, whether in prosecution, litigation, opposition, or third party observations: U.S. Applications 07/325,338 (filed March 17, 1989), 07/341,334 (filed April 20 1989), 07/353,896 (filed April 21, 1989), and 07/355,002 (filed May 18, 1989). The documents in the list below also includes other materials relied on during foreign oppositions.

**IV.A. List of materials cited in the Opposition to AUSTRALIAN Patent No. 640,920**

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- IV.B.9. Daniel W. Bradley v. Chiron Corp., et al.: Complaint: Civil Action No. C-94-4342 CW (cited above in I.A.)
- IV.B.10. A copy of the relevant portion of a report (April, 1995) on a biotechnology lawsuit. (cited above in I.A.)

IV.C. List of Art Cited by the Opponent during the Opposition to TAIWAN Patent Application No. 79102799

[This information was cited during the opposition against the TAIWAN application which claims priority from US Application Nos. 07/325,338, 07/353,896, 07/341,334, and 07/355,002]

- IV.C.1. Proc. Japan Acad., **65**, Ser. V. No. 9, pp. 219-223 (1989); (cited above at I.B.149) (cited above in I.A.)
- IV.C.2. Choo, et al., Science **244**:359-362 (1989) (previously considered in US/456,637, reference IT and EEO; and US 08/103,961, reference I.B.84; cited above as I.B.33)
- IV.C.3. Taiwan Patent Application No. 77108060 (Houghton, et al., subject to Taiwan Opposition 1; cited above at I.B.150)
- IV.C.4. Bradley, et al., Prog. Med. Virol. **37**:101-125 (1990) (cited by the examiner in 07/456,637, paper 23; and US 08/103,961, reference I.B.61; cited above as I.B.20)
- IV.C.5. Cha, et al., Proc. Natl. Acad. Sci. USA **89**:7144-7148 (1992) (previously considered in US 08/103,961, reference I.A.26; cited above as I.B.31)
- IV.C.6. Highfield, et al., GB Patent No. GB 2,239,245A (previously considered in US 07/456,637, on 9/28/92; and US 08/103,961, reference I.B.157; cited above as I.B.61)
- IV.C.7. Houghton, (Chiron Corp.), EP-A-0318216 (previously considered in US 07/456,637, reference GI; and US 08/103,961, reference I.B.163; cited above as I.B.64)



- IV.C.8. Kubo, et al., Nucleic Acids Res. **17**:10367-10372 (1989)  
(previously considered in US 07/456,637, reference JP; and US  
08/103,961, reference I.B.187; cited above as I.B.70)
- IV.C.9. Van der Poel, et al., The Lancet **337**:319 (1991) (previously  
considered in US 07/456,637, reference KS; and US 08/103,961,  
reference I.B.331; cited above as I.B.115)
- IV.C.10. Weiner, et al., The Lancet **335**:1-3 (1990) (previously considered  
in US 07/456,637, reference LL; and US 08/103,961, reference  
I.B.353; cited above as I.B.121)

**V. REFERENCES AND OTHER MATERIALS CITED TOWARDS REJECTIONS  
OF CLAIMS OR OBJECTIONS TO THE SPECIFICATION CORRESPONDING  
TO THE THIRD FOREIGN FILING**

The documets in the list below have been cited in a rejection of claims or an objection to the specification of one of the following U.S. Patent Applications or a corresponding foreign patent application or issued patent claiming priority from one of the following U.S. Patent Applications, whether in prosecution, litigation, opposition, or third party observations: U.S. Applications 07/355,961 (filed May 18, 1989), 07/456,637 (filed December 21, 1989), and 07/505,435 (filed April 4, 1990). The documents in the list below also includes other materials relied on during foreign oppositions.

**V.A. List of Art Cited Against the Claims by A U.S. Examiner**

- V.A.1. Bradley, et al., Prog. Med. Virol. **37**:101-135 (1990); (cited by the  
examiner in US 07/456,637, reference R paper 23; cited above as  
I.B.20)
- V.A.2. Berger, et al., U.S. Patent 4,891,313 (1990); (cited by the  
examiner in US 07/456,637, reference B paper 13; cited above as  
I.B.13)
- V.A.3. forrest, et al., US Patent 4,659,678 (1987); (Cited in US  
07/456,637, reference A paper 13; cited above as I.B.52)
- V.A.4. Mishiro, et al., U.S. Patent 5,077,193 (1991); (Cited in US  
07/456,637, reference A paper 23; cited above as I.B.76)
- V.A.5. Oellerich, J. Clin. Chem. Clin. Biochem. **22**:895-904 (1984);  
(Cited in US 07/456,637, reference R paper 13; cited above as  
I.B.82)

- V.A.6. Seto, et al., US Patent 4,673,634 (1987); (previously considered in US 07/122,174, US 07,139,886, US 07/161,072, US 07/191,263 (paper no. 5) and US 07/456,637, reference BA; cited above as I.B.102)
- V.A.7. Tabor, et al., J. Med. Virol. 4:161-169 (1979); (previously considered in US 07/456,637, reference RL, cited in paper 23; cited above as I.B.110)
- V.A.8. Villarejos, et al., US Patent 4,702,909 (1987); (previously considered in US 07/122,174, US 07/139,886, US 07/161,072, US 07/191,263 (paper no. 5), and US 07/456,637, reference BB; cited above as I.B.116)
- V.A.9. Young, et al., Proc. Natl. Acad. Sci USA. 80:1194-1198 (1983); (previously considered in US 07/456,637, reference FFM, cited by the examiner as reference S in paper 23; cited above as I.B.124)
- V.B. List of Art Cited Against the Claims During the Prosecution of PCT/US90/02853.  
[This information was cited during the prosecution of the PCT application which claims priority from US Application Nos. 07/355,961, 07/456,637, and 07/355,961]
- V.B.1. Mullis, et al., US Patent 4,683,195; (previously considered in US 07/355,961, 07/505,435; and US 08/103,961, reference I.B.218; cited above as I.B.78)
- V.B.2. Mullis, et al., US Patent 4,683,202; (previously considered in US 07/355,961, 07/505,435; and US 08/103,961, reference I.B.219; cited above as I.B.79)

VI. **INFORMATION FROM THE LITIGATION OF U.K. PATENT 2,212,511**

The following materials were selected from the vast materials relating to the UK litigation involving the UK counterpart of the six eldest ancestor applications. None of the claims in that patent, UK Patent No. 2,212,511 (listed as I.B.153, above), are directly analogous to the claims in the subject application; **i.e. immunoassays comprising antigens within the HCV genome.** Applicants provided this information to the U.S. Patent office as requested during an the interview with Examiner Sisson in the 08/103,961 application. This information was reviewed by Examiner Sisson, although not formally made of record on a PTO 1449 in the underlying application. Applicants are, herewith, submitting a PTO 1449 for these materials in this application.

Should the Examiner wish to review additional materials not previously provided or provided herewith, she is invited to contact the undersigned. Provided the Applicants have access to the materials and are not prevented by such confidentiality rules of the UK court, such materials will be supplied.

The Examiner should review initially the pleadings, the opening and closing speeches of counsel, and the Judgment (a copy of which was supplied during the interview). With respect to the pleadings, the final for the defendants' attack on the UK patent can be found in the pleadings at Bundle 2, tabs 14-16. The prior art relied upon in attacking the UK patent (listed above in II.B) can be found in Bundle 4, the front index of which sets out the prior art by type of attack (i.e., novelty, obviousness/common general knowledge, sufficiency). The novelty attack based on the Ross River Virus was dropped in the middle of trial.

Also included were similar affidavits that were produced in the course of a proceeding to obtain a preliminary injunction (called an interlocutory order) against the defendants.

VI.A. Affidavits and Trial Bundles from the Litigation of U.K. Patent No. 2,212,511

- VI.A.1. The Patent In Suit, UK Patent 2,212,511 for HEPATITIS C VIRUS (Houghton, et al.), patent published 1/22/92. (previously provided to the Patent office in US 08/103,961, reference III.A.1) (cited above in I.A.)
- VI.A.2. Amended Writ (Chiron Corp., et al. v. Organon Teknika, Ltd., et al. CH 1992 C No. 489) (previously provided to the Patent office in US 08/103,961, reference III.A.2) (cited above in I.A.)
- VI.A.3. Original Writ (Chiron Corp., et al. v. BCW Operations Ltd., CH 1992 C No. 1513) (previously provided to the Patent office in US 08/103,961, reference III.A.3) (cited above in I.A.)
- VI.A.4. Re-Amended Statement of Claim (Chiron Corp., et al. v. Organon Teknika Ltd., et al., CH 1992 C No. 489) (previously provided to the Patent office in US 08/103,961, reference III.A.4) (cited above in I.A.)

- VI.A.5. Amended Statement of Claim (Chiron Corp., et al. v. Murex Diagnostics Ltd., CH 1992 C No. 1513) (previously provided to the Patent office in US 08/103,961, reference III.A.5) (cited above in I.A.)
- VI.A.6. Amended Particulars of Infringement (Chiron Corp., et al. v. Organon Teknika Ltd., CH 1992 C No. 489)(previously provided to the Patent office in US 08/103,961, reference III.A.6) (cited above in I.A.)
- VI.A.7. Particulars of Infringement (Chiron Corp., et al. v. BCW Operations Ltd., CH 1992 C No. 1513) (previously provided to the Patent office in US 08/103,961, reference III.A.7) (cited above in I.A.)
- VI.A.8. Amended Defense and Counterclaim of the Fifth Defendant (Chiron Corp., et al. v. Organon Teknika Ltd., et al., CH 1992 C No. 489) (previously provided to the Patent office in US 08/103,961, reference III.A.8) (cited above in I.A.)
- VI.A.9. Re-Re-Re-Amended Particulars of Objections of the Fifth Defendant (Chiron Corp., et al., v. Organon Teknika Ltd., et al., CH 1992 C No. 489) (previously provided to the Patent office in US 08/103,961, reference III.A.9) (cited above in I.A.)
- VI.A.10. Amended Voluntary and Better Particulars of Insufficiency of Disclosure an Extension of Disclosure Under Particulars of Objections of the Fifth Defendant (Chiron Corp., et al. v. Organon Teknika Ltd., et al., CH 1992 C No. 489) (previously provided to the Patent office in US 08/103,961, reference III.A.10) (cited above in I.A.)
- VI.A.11. Amended Reply and Defense to Counterclaim of the Fifth Defendant (Chiron Corp., et al. v. Organon Teknika Ltd., et al. CH 1992 C No. 489) (previously provided to the Patent office in US 08/103,961, reference III.A.11) (cited above in I.A.)
- VI.A.12. Further and Better Particulars of the Amended and Re-Amended Replies and of the Amended Answer (Chiron Corp., et al. v. Organon Teknika Ltd., et al. and Murex Diagnostics Ltd., Consolidated Actions No. CH 1992 C No. 489, CH 1992 C No. 1513 and CH 1992 B No. 5552) (previously provided to the Patent office in US 08/103,961, reference III.A.12) (cited above in I.A.)

- VI.A.13. Notice Pursuant to the Civil Evidence Act 1968 and RSC Order 38, Rules 21 to 25 (Chiron Corp., et al. v. Organon Teknika Ltd., et al. and Murex Diagnostics Ltd., Consolidated Actions No. CH 1992 C No. 489, and CH 1992 C No. 1513) (previously provided to the Patent office in US 08/103,961, reference III.A.13) (cited above in I.A.)
- VI.A.14. Notice of Motion (Chiron Corp., et al. v. Organon Teknika Ltd., et al., CH 1992 C No. 489, 6/4/93) (previously provided to the Patent office in US 08/103,961, reference III.A.14) (cited above in I.A.)
- VI.A.15. Notice of Motion (Chiron Corp., et al. v. Organon Teknika Ltd., et al., CH 1992 C No. 489, 6/28/93) (previously provided to the Patent office in US 08/103,961, reference III.A.15) (cited above in I.A.)
- VI.A.16. Consolidated Defense and Counterclaim of all Defendants (Chiron Corp., et al. v. Organon Teknika Ltd., et al. and Murex Diagnostics Ltd., Consolidated Actions No. CH 1992 C No. 489, and CH 1992 C No. 1513) (previously provided to the Patent office in US 08/103,961, reference III.A.16) (cited above in I.A.)
- VI.A.17. Consolidated Particulars of Objections of all Defendants (Chiron Corp., et al. v. Organon Teknika Ltd., et al. and Murex Diagnostics Ltd., Consolidated Actions No. CH 1992 C No. 489, and CH 1992 C No. 1513) (previously provided to the Patent office in US 08/103,961, reference III.A.17) (cited above in I.A.)
- VI.A.18. Amended Notice Under Section 2 of the Civil Evidence Act 1968 (Chiron Corp., et al. v. Organon Teknika Ltd., et al. CH 1992 C No. 489) (previously provided to the Patent office in US 08/103,961, reference III.A.18) (cited above in I.A.)
- VI.A.19. Notice of Motion (Chiron Corp., et al. v. Organon Teknika Ltd., et al. and Murex Diagnostics Ltd., Consolidated Actions No. CH 1992 C No. 489, and CH 1992 C No. 1513, 6/30/93) (previously provided to the Patent office in US 08/103,961, reference III.A.19) (cited above in I.A.)
- VI.A.20. Notice of Motion (Chiron Corp., et al. v. Murex Diagnostics Ltd., CH 1992 C No. 1513, 4/8/93) (previously provided to the Patent office in US 08/103,961, reference III.A.20) (cited above in I.A.)
- VI.A.21. Notice of Motion (Chiron Corp., et al. v. Organon Teknika Ltd., et al., CH 1992 C No. 489, 4/8/93) (previously provided to the Patent office in US 08/103,961, reference III.A.21) (cited above in I.A.)

- VI.A.22. Affidavit of Gregor McIntyre Grant (Chiron Corp., et al. v. Murex Diagnostics Ltd., CH 1992 C No. 1513) (previously provided to the Patent office in US 08/103,961, reference III.A.22) (cited above in I.A.)
- VI.A.23. Fifth Affidavit of Christopher Peter Tootal (Chiron Corp., et al. v. Organon Teknika Ltd., et al. and Murex Diagnostics Ltd., Consolidated Actions No. CH 1992 C No. 489, and CH 1992 C No. 1513) (previously provided to the Patent office in US 08/103,961, reference III.A.23) (cited above in I.A.)
- VI.A.24. Affidavit of Laura A. Coruzzi filed 13 February 1992 with the High Court of Justice Chancery Division Patents Court, Case No. 489, Chiron Corp., Ortho Diagnostic Systems, Inc. and Ortho Diagnostic Systems Limited v. Organon Teknika Ltd.; (previously considered in US 07/456,637, reference FFK) (previously provided to the Patent office in US 08/103,961, reference III.A.24) (cited above in I.A.)
- VI.A.25. Affidavit of Professor Sir Aaron Klug, ScD, Hon FRCP, FRS, filed 13 February 1992 with the High Court of Justice Chancery Division Patents Court, Case No. 489, Chiron Corp., Ortho Diagnostic Systems, Inc. and Ortho Diagnostic Systems Limited v. Organon Teknika Ltd. (previously considered in US 07/456,637, reference FFL) (previously provided to the Patent office in US 08/103,961, reference III.A.25) (cited above in I.A.)
- VI.A.26. Faragher, Ph.D. thesis, Australian Natural University Lab, March, 1987 (previously considered in US 08/103,961, reference VI.27, cited above as I.B.48)
- VI.A.27. Okamoto, et al., Virology **188**:331-341 (1992) (previously considered in US 08/103,961, reference VI.28, cited above as I.B.83)
- VI.A.28. Vрати, et al., Virology **151**:222-232 (1986) (previously considered in US 08/103,961, reference VI.29, cited above as I.B.118)
- VI.A.29. Bankier, et al., Mol. Biol. Med. **1**:425-445) (1983) (previously considered in US 08/103,961, reference I.A.11; cited above as I.B.12)
- VI.A.30. Lopez, et al., Proc. Natl. Acad. Sci. USA **84**:5615-5619 (1987) (previously considered in US 08/103,961, reference I.A.56, cited above as I.B.71)
- VI.A.31. Rice, et al., Science **229**:726-733 (1985) (previously considered in US 08/103,961, reference I.A.69, cited above as I.B.92)

- VI.A.32. Backendorf, et al., Nucl. Acids Res. **14(7)**:2877 (1983) (previously considered in US 08/103,961, reference I.A.9, cited above as I.B.11)
- VI.A.33. Arikan, et al., Nucl. Acids Res. **14(6)**:2637 (1986) (previously considered in US 08/103,961, reference I.A.5, cited above as I.B.8)
- VI.A.34. Buttner, et al., Mol. Gen. Genet. **209**:101-109 (1987) (previously considered in US 08/103,961, reference I.A.25, cited above as I.B.27)
- VI.A.35. Molenaar, et al., Nucl. Acids Res. **12(19)**:7345 (1984) (previously considered in US 08/103,961, reference I.A.59, cited above as I.B.77)
- VI.A.36. Nakada, et al., Virus Res. **1**:433-441 (1984) (previously considered in US 08/103,961, reference I.A.62; cited above as I.B.80)
- VI.A.37. Yaegashi, et al., Gene **46**:257-267 (1986) (previously considered in US 08/103,961, reference I.A.89; cited above as I.B.123)
- VI.A.38. Bradley, et al., Gastroenterology **88**:773-779 (1985) (previously considered in US 08/103,961, reference I.B.51; cited above as I.B.16)
- VI.A.39. Bradley, et al., J. Virol. Meth. **10**:307-319 (1985) (previously considered in US 08/103,961, reference I.B.45; cited above as I.B.15)
- VI.A.40. Bradley, et al., Seminars in Liver Disease **6(1)**:56-66 (1986) (previously considered in US 08/103,961, reference I.B.62; cited above as I.B.21)
- VI.A.41. Bradley, et al., J. Med. Virol. **3**:253-269 (1979) (previously considered in US 08/103,961, reference I.B.56; cited above as I.B.18)
- VI.A.42. Weiner, et al., J. Med. Virol. **21**:239-247 (1987) (previously considered in US 08/103,961, reference I.B.350; cited above as I.B.120)
- VI.A.43. Rice, et al., Science **229**:726-733 (1985) (previously considered in US 08/103,961, reference I.A.69; cited above as I.B.92)
- VI.A.44. Aaskov, et al., J. Immu. Meth. **25**:37-41 (1979) (previously considered in US 08/103,961, reference I.A.2; cited above as I.B.5)
- VI.A.45. Edwards, Immunoassay: An Introduction (London, 1985) (previously considered in US 08/103,961, reference I.A.32; cited above as I.B.46)

- VI.A.46. O'Sullivan, Clinical and Biochemical Analysis, Vol. 14, Chpt. 3 (1984) (previously considered in US 08/103,961, reference I.A.66; cited above as I.B.85)
- VI.A.47. Schuurs, et al., Clin. Chem. ACTA **81**:1-40 (1977) (previously considered in US 08/103,961, reference I.A.74; cited above as I.B.97)
- VI.A.48. Young, et al., Proc. Natl. Acad. Sci. USA **80**:1194 (1983) (previously considered in US 08/103,961, reference I.B.358; cited above as I.B.124)
- VI.A.49. Kemp, et al., Proc. Natl. Acad. Sci. **80**:3787 (1983) (previously considered in US 08/103,961, reference I.A.95; cited above as I.B.68)
- VI.A.50. Stahl, et al., Proc. Natl. Acad. Sci. USA **81**:2456 (1984) (previously considered in US 08/103,961, reference I.A.80; cited above as I.B.107)
- VI.A.51. Huynh, et al., DNA Cloning, Vol. 1, Chpt. 2, p. 49 (1985) (previously considered in US 08/103,961, reference I.A.95; cited above as I.B.66)
- VI.A.52. Davis, et al., Proc. Natl. Acad. Sci. USA **83**:5534 (1986) (previously considered in US 08/103,961, reference I.A.30; cited above as I.B.39)
- VI.A.53. Guerin-Marchand, Nature **329**:164 (1987) (previously considered in US 08/103,961, reference I.B.143; cited above as I.B.56)
- VI.A.54. Scallon, et al., Mol. Biochem. Parasitology **24**:237 (1987) (previously considered in US 08/103,961, reference I.A.73; cited above as I.B.96)
- VI.A.55. Olds, et al., Principles of Gene Manipulation 3rd Ed. p. 113 (1985) (previously considered in US 08/103,961, reference I.A.65; cited above as I.B.8)
- VI.A.56. Mierendorf, et al., Methods of Enzymology, Chpt. 51, Vol. 152 (1987) Berger & Kimmel (eds) (previously considered in US 08/103,961, reference I.A.12; cited above as I.B.14)
- VI.A.57. Houghton, et al., Hepatology **14**(2):381 (1991) (previously considered in US 08/103,961, reference I.A.47; cited above as I.B.63)
- VI.A.58. Faragher, et al., Virology **163**:509 (1988) (previously considered in US 08/103,961, reference I.A.35; cited above as I.B.50)
- VI.A.59. Witness Statement of Michael Houghton (cited above in I.A.)



- VI.A.60. Witness Statement of Amy Joan Weiner (cited above in I.A.)
- VI.A.61. Witness Statement of George Kuo (cited above in I.A.)
- VI.A.62. Witness Statement of Michael Joseph McGarvey (cited above in I.A.)
- VI.A.63. Affidavit of Robert Tjian (cited above in I.A.)
- VI.A.64. Supplemental Witness Statement of Amy Joan Weiner (cited above in I.A.)
- VI.A.65. Expert's Report of William J. Brammar (cited above in I.A.)
- VI.A.66. Expert's Report of Howard Christopher Thomas) (cited above in I.A.)
- VI.A.67. Experts Report of Harold Eliot Varmus (cited above in I.A.)
- VI.A.68. Supplemental Expert's Report of William J. Brammar (cited above in I.A.)
- VI.A.69. Supplemental Expert's Report of Howard Christopher Thomas (cited above in I.A.)
- VI.A.70. Annexure 1 to the Witness Statement of Michael Houghton—Michael Houghton CV (cited above in I.A.)
- VI.A.71. Annexure AJW-1 to Witness Statement of Amy Joan Weiner—New York Times 5/11/88 (cited above in I.A.)
- VI.A.72. Annexure GK-1 to the Witness Statement of George Kuo—George Kuo CV (cited above in I.A.)
- VI.A.73. Annexure GK-2 to the Witness Statement of George Kuo—Quote regarding "snarks" (cited above in I.A.)
- VI.A.74. Annexure MJM-1 to Witness Statement of Michael Joseph McGarvey—McGarvey, et al., Proc. Natl. Acad. Sci. USA, **81**:3690 (1984) (cited above in I.A.)
- VI.A.75. Annexure MJM-2 to Witness Statement of Michael Joseph McGarvey—Award to McGarvey from the Nuffield Foundation (cited above in I.A.)
- VI.A.76. Annexure MJM-3 to Witness Statement of Michael Joseph McGarvey—The Guardian, 5/12/88 (cited above in I.A.)
- VI.A.77. Annexure MJM-4 to Witness Statement of Michael Joseph McGarvey—New Scientist, May 26, 1988 (cited above in I.A.)

- VI.A.78. Annexure MJM-5 to Witness Statement of Michael Joseph McGarvey—McGarvey, et al., J. Hepatol. **13(Supp. 2)**:S52 (cited above in I.A.)
- VI.A.79. Annexure 1 to Witness Statement of William J. Brammar—William J. Brammar CV (cited above in I.A.)
- VI.A.80. Annexure 2 to Witness Statement of William J. Brammar—Broome, et al., Proc. Natl. Acad. Sci. USA **75(6)**:2746 (1978) (cited above in I.A.)
- VI.A.81. Annexure 3 to Witness Statement of William J. Brammar—Williams, et al., J. Med. Virol. **24**:263 (1988) (cited above in I.A.)
- VI.A.82. Annexure 4 to Witness Statement of William J. Brammar—Bradley, et al., J. Med. Virol. **34**:206 (1991) (cited above in I.A.)
- VI.A.83. Annexure 5 to Witness Statement of William J. Brammar—Geysen, et al., Proc. Natl. Acad. Sci. USA **81**:3998 (1984) and Geysen, et al., J. Immu. Meth. **102**:159 (1987) (cited above in I.A.)
- VI.A.84. Annexure 6 to Witness Statement of William J. Brammar—A Dictionary of Genetic Engineering, p. 49 (1985) (cited above in I.A.)
- VI.A.85. Annexure 7 to Witness Statement of William J. Brammar—Package insert for Hepatitis C virus enzyme immunoassay (cited above in I.A.)
- VI.A.86. Annexure 8 to Witness Statement of William J. Brammar—Fig. 14-1, combined ORF of DNAs (cited above in I.A.)
- VI.A.87. Annexure 9 to Witness Statement of William J. Brammar—Choo, et al. Proc. Natl. Acad. Sci. USA **88(6)**:2451 (1991) (cited above in I.A.)
- VI.A.88. Annexure 10 to Witness Statement of William J. Brammar—UBI Manufacturing Document (cited above in I.A.)
- VI.A.89. Annexure HCT-1 to Witness Statement of Howard Christopher Thomas—Howard Christopher Thomas CV (cited above in I.A.)
- VI.A.90. Annexure HCT-2 to Witness Statement of Howard Christopher Thomas—Historical listing of references over time to specific issues (cited above in I.A.)

- VI.A.91. Annexure HCT-3 to Witness Statement of Howard Christopher Thomas—Thomas, Quarterly J. Med. **65(246)**:793 (1987) (cited above in I.A.)
- VI.A.92. Annexure HCT-4 to Witness Statement of Howard Christopher Thomas—Bamber, et al, Med. Lab. Sciences **38**:373 (1981) (previously considered in US 08/103,961, reference I.B.43)
- VI.A.93. Annexure HCT-5 to Witness Statement of Howard Christopher Thomas—Luo, et al., J. Med. Virol. **12**:253 (1983) (previously considered US 08/103,961, reference I.B.198)
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- VI.A.155. Annexure AJW-8 to Witness Statement of Amy Joan Weiner—Lab Notebook pages from Book 5547 (cited above in I.A.)
- VI.A.156. Annexure AJW-9 to Witness Statement of Amy Joan Weiner—Amy Weiner CV (cited above in I.A.)
- VI.A.157. Expert Report of Professor J.W. Almond (cited above in I.A.)
- VI.A.158. Expert Report of Dr. Timothy John Harrison (cited above in I.A.)
- VI.A.159. Expert's Report - Dr. Nicholas Clwyd Jones (cited above in I.A.)
- VI.A.160. Witness Statement of Professor Sir Aaron Klug (cited above in I.A.)
- VI.A.161. Witness Statement of Professor Baruch S. Blumberg (cited above in I.A.)

- VI.A.162. Statement of Dr. Gregory R. Reyes (cited above in I.A.)
- VI.A.163. Witness Statement - Professor Terukatsu Arima (cited above in I.A.)
- VI.A.164. First Affidavit of Dr. John Gregory Aaskov (cited above in I.A.)
- VI.A.165. Statement by Michael J. Evans (cited above in I.A.)
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- VI.A.256. Arima, et al., (The Research Foundation for Microbial Diseases of Osaka University), EP 0363025 (4/11/90) (cited above in I.A.)
- VI.A.257. Affidavit of Ian Armitage—(with Exhibits) (cited above in I.A.)
- VI.A.258. Affidavit of Professor Baruch Samuel Blumberg—(with Exhibits) (cited above in I.A.)
- VI.A.259. Affidavit of Laura A. Coruzzi—(with Exhibits) (cited above in I.A.)
- VI.A.260. Affidavit of Douglas Michael Goldin—(with Exhibits) (cited above in I.A.)
- VI.A.261. Affidavit of Professor Sir Aaron Klug, ScD, Hon FRCP, FRS—(with Exhibit) (cited above in I.A.)
- VI.A.262. Affidavit of William J. Rutter—(with Exhibits) (cited above in I.A.)
- VI.A.263. Affidavit of Dame Shiela Patricia Violet Sherlock—(with Exhibits) (cited above in I.A.)
- VI.A.264. Affidavit of Martha Ann Truett—(with Exhibits) (cited above in I.A.)
- VI.A.265. Affidavit of Douglas Michael Goldin—(with Exhibits) (cited above in I.A.)
- VI.A.266. Affidavit of Peter Edmund Highfield—(with Exhibits) (cited above in I.A.)
- VI.A.267. Affidavit of Judith Silveston—(with Exhibits) (cited above in I.A.) Affidavit of Richard Seton Tedder—(with Exhibits) (cited above in I.A.)
- VI.A.268. UK Trial Transcript speeches Volume S1 through S7, Monday July 5, 1993 through Monday August 2, 1993 (cited above in I.A.)
- VI.A.269. UK Trial Transcript Evidence, Volume E1 through E15, Tuesday July 6, 1993 through Monday July 26, 1993 (cited above in I.A.)
- VI.A.270. Witness statements and testimony (examination and cross-examination) of Drs. Houghton, Kuo, Weiner, McGarvey, Reyes and Caput; and (cited above in I.A.)

VI.A.271. The Expert reports and testimony (examination and cross-examination) of Drs. Brammar, Thomas, Varmus, Almond, Harrison, Jones, Klug and Blumberg. (cited above in I.A.)

Applicants request that the Examiner initial and return the form PTO-1449, indicating that the references and materials provided herewith or in the cross-referenced earlier applications have indeed been considered and made of record herein.

This Information Disclosure Statement under 37 CFR §1.97 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention. Please charge any fees or credit any overpayment to Deposit Account No. 03-1664. This, however, is not an authorization for payment of any issue fees.

Respectfully submitted,

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